APR - 9 2004

K040599

## 510(k) SUMMARY

**Submitter:**

Parkell, Inc.
155 Schmitt Blvd.
Box 376
Farmingdale, NY 11735
TEL: 631-249-1134
FAX: 631-249-1242

**Contact:**

Nelson J. Gendusa, DDS
Director of Research
Parkell
155 Schmitt Blvd.
Box 376
Farmingdale, NY 11735

**Submission Date:** 15 April 2003

**Trade Name:** Currently Not Available

**Common Name:** Resin Glaze

**Classification Name:** Coating, Filling Material, Resin

**Equivalence:** belleGlaze, LuxaGlaze, Biscover XT, Biscover Polish

**Description/Intended Use:** A nano-filled, light-cured, clear resin intended for use by a duly licensed professional as a glaze and sealer for composite resin restorations or for acrylic, bis-acryl and/or composite temporary materials. It can be used to impart high sheen and seal to appropriate surfaces. Cures without oxygen-inhibition and is expected to extend restoration durability and resistance to abrasive wear. This material is substantially equivalent to other FDA-certified devices (cited above) marketed in the USA. It functions in a manner similar to them and is intended for the same use as these predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 9 2004

Dr. Nelson J. Gendusa
Director of Research
Parkell, Incorporated
155 Schmitt Boulevard
Farmingdale, New York 11735

Re: K040599
Trade/Device Name: Resin Glaze
Regulation Number: 21 CFR 872.3310
Regulation Name: Coating Material for Resin Fillings
Regulatory Class: II
Product Code: EBD
Dated: April 01, 2004
Received: April 05, 2004

Dear Dr. Gendusa:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Chiu S. Lin, PhD
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

**510(k) Number (if known):** K040599

**Device Name:** Resin Glaze

**Indications For Use:** A nanofilled, light-cured, clear resin intended for use by a duly licensed professional as a glaze and sealant for composite resin restorations or for acrylic, bis-acryl and/or composite temporary materials. It can be used to impart high sheen and seal to appropriate surfaces without oxygen-inhibition and is expected to extend restoration durability and resistance to abrasive wear. This material is substantially equivalent to other FDA-certified devices (cited above) marketed in the USA. It functions in a manner similar to them and is intended for the same use as these predicate devices.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert Buch DDS for Dr. Susan Runner
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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